

# UNIVERSITY OF HAWAI‘I CANCER CENTER CONNECTION

## University of Hawai‘i Cancer Center: Collaboration Through Partnership with the National Cancer Institute

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The University of Hawai‘i Cancer Center (UHCC) is the only National Cancer Institute (NCI)-designated Cancer Research Center serving Hawai‘i and the Pacific. This past year, UHCC successfully attained renewal of its Minority/Underserved NCI Community Oncology Research Program (M/U NCORP) grant. The NCORP and its predecessor, the Minority Based-Community Clinical Oncology Program (MB-CCOP) have provided funding to support cancer clinical trials infrastructure in the state of Hawai‘i since 1994. We will describe the history of the NCI-sponsored clinical trial program, specifically how it relates to Hawai‘i. We will also provide numerous examples of clinical trials that are particularly relevant to the people of Hawai‘i that have been made available through the CCOP and NCORP mechanisms.

### **The History of NCI-sponsored Cancer Clinical Trials at Community Cancer Centers**

Recognizing that 85% of cancer patients are treated in the community setting, the NCI established the Community Clinical Oncology Program (CCOP) to provide opportunity for participation on NCI-sponsored clinical trials in the community and to help increase accrual to cancer research studies nationwide. To ensure that clinical trial participation was available to patients of racial minority groups, the NCI created a parallel program of centers that care for a large portion of racial minority patients called the Minority Based CCOP (MB-CCOP). The University of Hawai‘i Cancer Center was awarded its first MB-CCOP grant in 1994 under the direction of Dr. Brian Issell.

The NCI created the National Community Cancer Centers Program (NCCCCP) in 2007 to focus on improving the quality of cancer care delivered at community cancer clinics throughout the United States (US). The Queen’s Medical Center was selected as an NCCCCP participant in 2010 with Dr. Paul Morris serving as principal investigator (PI).

In 2014, the NCI created the NCI Community Oncology Research Program (NCORP) that combined the research focus of

the CCOP and the cancer care delivery and health care disparities emphasis of the NCCCCP. The University of Hawai‘i was one of the first 12 sites to be awarded a Minority/Underserved NCORP (M/U NCORP) grant with Dr. Jeffrey Berenberg as contact PI. Dr. Morris served as co-PI in charge of overseeing Cancer Care Delivery Research. The most recent round of NCORP grants were awarded this year to 53 sites (including UH and 13 other M/U NCORP sites) and covers patients in 44 states, Puerto Rico, and Guam.

In its initial grant period from 2014-2019, the NCORP program has succeeded in enrolling more than 37000 patients in cancer studies across 49 sites. These include studies involving all aspects of cancer medicine: screening, prevention, symptom control, cancer care delivery, and treatment trials. Achievements included addressing clinical problems such as chemotherapy induced nausea and vomiting (CINV). A study of olanzapine to prevent CINV in patients treated at the Hawai‘i M/U NCORP and other NCORP sites demonstrated that olanzapine significantly reduced the risk of CINV and altered the standard of care.

The studies presented below provide examples of the work done at the UH Cancer Center.

### **NCI Cancer Clinical Trials in Hawai‘i and Soon Guam**

The Hawai‘i M/U NCORP provides the financial and personnel infrastructure to facilitate cancer clinical trial participation in Hawai‘i, supporting over two-thirds of the cancer patients in the state each year. The 6-year \$8 million grant awarded to the Hawai‘i M/U NCORP provides the people of Hawai‘i access to NCI sponsored cancer clinical trials. Dr. Berenberg is the contact PI for the NCORP grant for this most recent award cycle, and Drs. Jared Acoba and Randall Holcombe serve as Multiple-PIs.

To deliver clinical trial opportunities across the state, the Hawai‘i M/U NCORP partners with large private hospital systems including The Queen’s Medical Center, Hawai‘i Pacific Health,

Kuakini Medical Center, as well as Tripler Army Medical Center and the largest private radiation and medical oncology practices on O'ahu, the Cancer Center of Hawai'i, Hawai'i Cancer Care, and Hawai'i Oncology Incorporated. In addition, the new grant provides the opportunity for patients in Guam to have access to the NCI clinical trials for the first time. This effort is led by Dr. Berenberg and Virginia McMahon in Hawai'i and Dr. Samir Ambrale in Guam. For patients in Hawai'i and Guam, the importance of having clinical trial opportunities close to home cannot be underscored enough, as the next nearest site for cancer clinical trials is nearly 2500 miles away.

### **Trials for People at Risk for Cancer, Cancer Patients, and Cancer Survivors in Hawai'i**

There are many examples of NCORP clinical trials that are specifically applicable to the people of Hawai'i. Breast cancer is the most common malignancy among women in Hawai'i. Screening mammograms help to detect breast cancer at an early stage when it is easiest to treat. Recently, a newer imaging technique, digital breast tomosynthesis, has become available in Hawai'i. Retrospective data suggest that, compared with standard digital mammography, tomosynthesis offers better detection of invasive breast cancers and leads to fewer additional imaging studies for false-positives (lesions that appear to be cancer but are actually benign).<sup>1</sup> However, this benefit has not yet been confirmed in a prospective study, and tomosynthesis does come with a higher financial cost as well as a modest increase in radiation dose.<sup>2</sup> The national Tomosynthesis Mammographic Imaging Screening Trial (TMIST) is a prospective randomized study that will compare the utility of digital mammography versus tomosynthesis in detecting advanced breast cancers. TMIST is open in Hawai'i through the Hawai'i M/U NCORP as well as The Queens Medical Center and allows women in Hawai'i to participate in this potentially paradigm-changing study to determine the most effective breast cancer screening test. UH is partnering with the NCI to increase participation of Micronesian women in Hawai'i.

Hawai'i has one of the highest rates of cholangiocarcinoma in the US, and this has led the Hawai'i State Legislature to grant \$350,000 to the UH Cancer Center to investigate cancers in the hepatobiliary tract such as cholangiocarcinoma. Many patients with cholangiocarcinoma present with advanced disease for which chemotherapy is the optimal treatment option. SWOG 1815 is an NCORP clinical trial comparing the standard chemotherapy regimen of cisplatin and gemcitabine with the novel combination of cisplatin, gemcitabine, and nab-paclitaxel, a combination that has displayed an excellent response rate and will hopefully improve survival. The Hawai'i M/U NCORP has accrued the most patients to this study thus far among all community cancer centers in the US.<sup>3</sup>

Other clinical trials available through the NCORP that are particularly relevant to the population of the state include studies on older adults and obese patients. Hawai'i ranks as the 16<sup>th</sup> oldest state with 13.3% of the population over 65 years of age. The Hawai'i M/U NCORP opened a clinical trial, URCC13059, that aims to decrease the morbidity of older adults undergoing cancer treatment through use of a modified geriatric assessment. Native Hawaiians have an increased cancer mortality rate attributed in part to higher rates of obesity and hypertension, as well as other genetic and life-style risk factors. In response, A011401 (BWEL) trial was opened to address this problem. This trial is a 2-year diet and life-style modification study to improve breast cancer outcomes among obese women.

NCORP participation has also made trials available to cancer survivors. For example, one trial aims to improve quality of life for head and neck cancer survivors, and another trial aims to decrease the risk of cancer recurrence for colon cancer survivors in Hawai'i. Head and neck cancer survivors often suffer from radiation-induced xerostomia – persistent dry mouth as a consequence of their radiation therapy. These patients may be eligible for an NCORP study, sponsored by the Wake Forest research base, that offers acupuncture as a therapy to increase saliva production. In part because acupuncture is a widely accepted treatment among the people of this state, the Hawai'i M/U NCORP has been one of the highest accruing sites for this trial. Colon cancer is the second leading cause of cancer death in Hawai'i. SWOG 0820 is a clinical trial for colon cancer survivors that is utilizing the combination of sulindac and eflornithine as a treatment to prevent the occurrence of new colon cancers and precursor polyps.

### **Cancer Care Delivery Research: Studies Aimed to Improve the Patient Experience**

As an extension of the NCCCP program, the NCORP includes Cancer Care Delivery Research (CCDR) studies that aim to improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence care delivery with an emphasis on diagnosis, treatment, survivorship, and end-of-life care. One example of a CCDR trial is A231701CD, a study for women undergoing surgery for breast cancer. The goal of the study is to use a decision aid to increase patient engagement in decision making for patients with newly diagnosed stage 0-III breast cancer. The study specifically assesses barriers faced by socioeconomically disadvantaged patients. Through the coordination of efforts of research staff at UHCC and Hawai'i Pacific Health, 26 patients have been enrolled into this trial.

## **NCORP Trials Shaping Cancer Medicine into the Future**

Between 1980-2017, 43% of all NCI-sponsored trials influenced the practice of clinical oncology. An estimated 3.3 million years of life have been gained as a result of these studies at a reasonable cost of \$125 per life-year gained.<sup>4</sup> Having access to these trials is extremely important to patients as it offers them access to up-to-date treatment strategies and novel medications. The Hawai‘i M/U NCORP has been offering access to these trials to the people of Hawai‘i for the last 25 years. Through collaboration with its clinical partners, the NCORP will continue to provide this critical service for the next several years and beyond.

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